



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504
December 29, 2015
Pharmacy Quality Assurance Commission
Special Meeting – Audio Conference
Highlights

Commissioners (Panelist)

Al Linggi, R.Ph., Chair
Dan Rubin, MPP, Vice-Chair (Public Member)
Tim Lynch, Pharm.D., MS
Steve Anderson, BSpHarm., R.Ph.
Gary Harris, R.Ph.
Chris Barry, R.Ph.
Olgy Diaz, Public Member
Maureen Sparks, CPhT.
Matthew Ronayne, R.Ph.
Judy Guenther, Public Member
Cheryl Adams, Pharm.D.
Elizabeth Jensen, Pharm.D.
Nancy Hecox, Pharm.D., CDP
Arun Sambataro, Public Member-absent
Sepi Soleimanpour, Pharm.D., MBA-HA - absent

Staff

Lisa Hodgson, HPF Director
Cathleen Williams
Lisa Roberts
Rich Cieslinski
Doreen Beebe
Irina Tiginyanu
Leann George
Gordon MacDonald
Tyler Varnum
Kyle Karenin
Tracy West
Danielle Welliever
Tim Farrell
Joyce Roper, AAG

Attendees (by webinar)

Billy Chow	Shelley Rogers
Carolyn Logue	Sheri Healey
Chris Terriff	Teri Ferreira
Cindy Wilson	William Hayes
David Lewis	
Dedi Little	
Dennis McAllister	
Greg legore	
Greg Gibbons	
Ian Corbridge	
Jeff Rochon	
Jeffrey Vogan	
Joanie Deutsch	
Karen Nishi	
Kenneth Kenyon	
Kristine Gibson	
Larry Oliver	
Lauren Berton	
Leonard Bergstein	
Linda Howrey	
Lis Houchen	
Lisa Feldhaus	
Margaret Pagel	
Mike Bonck	
Neal Watson	
Neil Marshall	
Ron Friedman	
Sally Logan	
Sandra Dal	
Shannon Lawson	

The meeting was called to order at 1:03 PM.

A special meeting of the Pharmacy Quality Assurance Commission was held to consider a proposal by EvergreenHealth – Monroe for the use of automated drug distribution devices, and to discuss statutory updates for possible legislation.

- To help manage the review, the Chair proposed that members categorized recommended changes with the focus on patient safety. Categories were identified as 1) patient safety issue, 2) potential patient safety or technology related, and 3) all others.

Category 1 Recommendations:

1. [Chapter 18.64 RCW](#) Pharmacists (Pharmacy Practice Act)
 - Need to add authority to regulate the practice of virtual wholesalers – What is the role they play in the distribution chain that could impact patient safety. Concern associated with grey markets, and drugs.
 - Mirror inspection requirements as listed below for non-resident pharmacies for all out-of-state pharmaceutical firms.
2. RCW [18.64.360](#), [370](#), [380](#) – Non-resident pharmacies.
 - Require on-site inspections every two years, requirement for renewal
 - Inspection conducted by the regulatory authority of the resident state or the National Association of Boards of Pharmacy, Verified Pharmacy Program
 - Costs of inspections incurred by the pharmacy
 - Washington Licensed Pharmacist in Charge – (not fully supported)
3. RCW [18.64.390](#) - Non-resident pharmacies –violations.
 - Increase fine to “not to exceed \$2500 per violation for failure to comply...
 - Increase fine to “not less than \$2500 or more than \$100,000 per violation for conduct that causes serious bodily or psychological injury to a resident of this state ...
4. [RCW 69.41.055](#) – Electronic communication of prescription information: A fax machine is not considered to be an electronic device, but this may preclude a patient from getting a prescription if the pharmacy does not have the adequate electronic software to accept the electronic prescription.
5. [RCW 69.50.101](#) – Electronic communication of prescription information: A fax machine is not considered to be an electronic device, but this may preclude a patient from getting a prescription if the pharmacy does not have the adequate electronic software to accept the electronic prescription. (This may need further discussion/research to ensure it is not in conflict with federal Drug Enforcement Administration rules on electronic communication of prescriptions for controlled substances).

Category 2 Recommendations

1. RCW [18.64.165](#) – Refusal, Suspension, Revocation of other licenses.
 - Currently we only have the ability to suspend or revoke a facility license. Many times the violations do not warrant this type of extreme action. Need ability to

assess fines/financial penalties. See suggested language fine amounts for RCW18.64.390

2. RCW [18.64A.030](#) – Duties of Technicians, Assistants
 - Chapter title is confusing – should read “ Pharmacy Ancillary Staff.”
 - Suggest more general description of duties rather than the detailed task list provided for pharmacy assistants. It is better to have specific tasks in WAC rather than in RCW since the practice of pharmacy changes.
 - It should be clarified that pharmacy assistants may only print a label where there is no manipulation to the patient record information. A pharmacy assistant may only type a label for a new prescription if they are in-training in a Commission-approved technician training programs.

Category 3 Recommendations

1. RCW [18.64.001](#)– Pharmacy Quality Assurance Commission - creation
 - Pilot project as independent authority/autonomy (e.g. Medical Quality Assurance Commission or Nursing Care Quality Assurance Commission)
2. RC W 18.64.003 - Designation as a class five commission – this is consistent with all other commissions representing health professions. This would increase members compensation pay to \$250 per day.
3. RCW 18.64.005 – Commission powers and duties. Subsection 13 may need clarification as it interjects the “department” where the duties should refer to the commission.
4. RCW 18.64.009 - Enforcement employees declared to be peace officers—Authority – Joyce Roper will provide language to narrow the authority and meet the needs of the commission.
5. RCW 18.64.011- Definitions – Add:
 - Outsourcing facility
 - Third Party Logistic Provider
 - Virtual Distributor
 - Trace
 - Licensing structure needs to be reviewed – all pharmacies currently are grouped in one category. (e.g. remote and telepharmacy practices) In addition, consider changes to the practice of pharmacy to corporate practice outside of a pharmacy setting.
6. RCW 18.64.043 – Pharmacy License – Consider remove misdemeanor language, which is much more than just an administrative violation for failure to comply. This issue may apply to other statutes/sections.
7. RCW 69.70.010 - Access to Prescription Drugs (Donated Drugs) – review law for impact of federal laws related to trace and trace.

The commission discussed other statutes that were not categorized. This discussion was a preliminary exercise in the commission’s ongoing review of pharmacy statutes. Stakeholders are encouraged to provide comments and suggestions regarding other areas of pharmacy statutes that may need updates.

EvergreenHealth – Monroe

Commissioner Barry moved that the Commission approve the use of ADDDs (policies and procedures) by EvergreenHealth – Monroe with services to its residential treatment facility newly licensed as a Health Care Entity. Motion seconded by Commissioner Adams. Vote 13-0.


Action Items:

- Steve Anderson will provide members with categories of laws that are required of Washington pharmacies operating in other states.
- Commission will review NABP Model Act regarding Virtual Manufacturers.
- Stakeholder request documentation to support fees/penalties for pharmaceutical firms.
- Commissioner Lynch requests the commission develop a communication to clarify that the use of automated drug distribution devices in licensed health care entities.

The meeting adjourned at 3:03 p.m.

Respectfully Submitted by:

Doreen Beebe, Program Manager



Tim Lynch, Pharm.D., MS, Chair
Pharmacy Quality Assurance Commission